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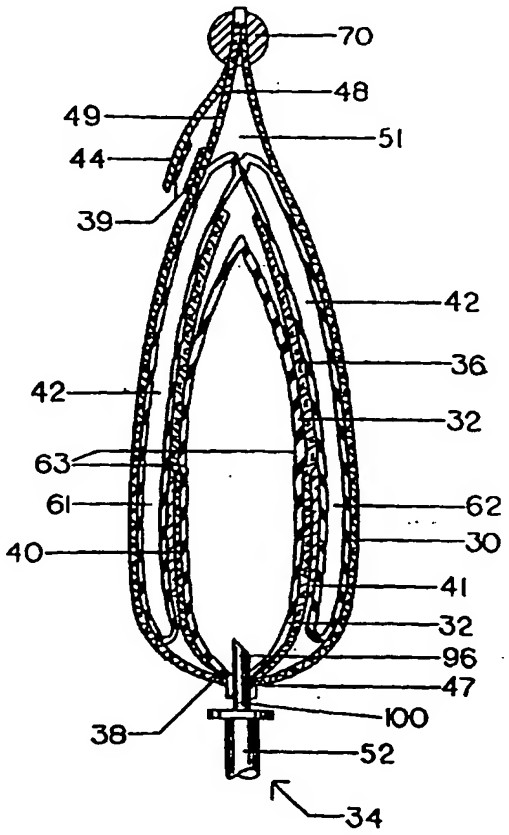
(54) Title: IRRIGATION SYSTEM FOR PREVENTING HYPOTHERMIA

(57) Abstract

The invention concerns a surgical apparatus for irrigating an operative site during endoscopic surgery. The apparatus comprises a reservoir of irrigation fluid (32) contained within an air actuated pouch (30), a pump (54) for inflating the pouch so that the reservoir is compressed, pressure control means (20), a microprocessor (53) for operating the system, heating panels (40) contained within the pouch for providing heated irrigation fluid, and a nozzle and tube (52) for delivering the irrigation fluid to an operative site. The apparatus also provides a stick fitting (100) for attaching tubing to the fluid reservoir. In addition to the stick fitting, the apparatus provides a locking receiver system for ensuring that the stick fitting will not disengage during use.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IRRIGATION SYSTEM FOR PREVENTING HYPOTHERMIA

FIELD OF THE INVENTION

This invention generally relates to the field of irrigation delivery systems, and, more particularly, to an improved irrigation delivery system that heats the irrigation fluid, provides the irrigation fluid under higher pressures, and prevents contamination of the sterile irrigation fluid.

BACKGROUND OF THE INVENTION

Irrigation of a surgical or operative site accomplishes three goals. First, flushing the site with fluid cleans the area of blood and tissue providing a surgeon with an improved view. Secondly, the fluid functions as a medium for removal of blood and debris during aspiration of the operative site. Thirdly, pressurized irrigant is used to gently separate anatomical structures for accessing adjacent structures. High pressure irrigant is desired for use in laser surgery, however, well known systems cannot provide sufficient pressure for that use.

Irrigation delivery systems typically include measurement and control instruments to adjust flow rates, a reservoir for the sterile irrigation fluid, a pump or other flow producing means, a flexible sterile conduit, and an operative instrument for discharging fluid to an operative site.

Well known irrigation systems include gravity systems, pressurized gas systems, various mechanical pump designs, and pressure vessel compression systems. The gravity systems usually suspend the irrigation fluid at an elevated height to produce fluid flow. A problem associated with gravity systems is that, typically, these systems cannot achieve high flow rates.

Pressurized gas systems pump gas into a sterile fluid container and force the fluid out of the container, through a conduit and into an operative instrument for delivery to the operative site. A problem with gas systems is that the gas contacts the sterile fluid and may introduce contaminants into the fluid. Another problem with these systems is cross-flow contamination. Cross-flow contamination occurs when contaminated fluid at the operative site backflows into the sterile conduit.

Mechanical pumps include complex pneumatic, systolic, and peristaltic pumps as well as disposable sterile pumps. Pumps are generally undesirable because they are not self contained, operate at high noise levels, and contaminate the sterile irrigation fluid.

A pressure vessel system utilizes a rigid housing for holding a flexible fluid bag. Flow is achieved by pressurizing the area within the housing with either gas or fluid such that the bag is compressed. Problems associated with these systems are a small irrigant capacity and contamination at the interfaces between the housing and the tubing connected to the housing. In addition, this type of system is often undesirable because it utilizes a hospital's gas supply line which limits the system's mobility and makes the gas supply line unavailable for other uses.

It is desirable to have irrigation fluid preheated to prevent patient hypothermia, however, there are frequently pre-surgery delays during which the fluid cools. Consequently, a system capable of maintaining fluid at its preheated temperature is desired. One system that has attempted to solve this problem is a heated water bath where the bags of irrigant are immersed in the bath and fluid is pumped from the bag up through the control system. However, disadvantages associated with this system

are that the system is not self contained, is cumbersome, and is inconvenient. Another system provides a sleeve having a heating element that slides over a portion of the tubing so that fluid is heated as it travels through that portion of the tubing. Problems associated with this system are that the preheated temperature is not maintained and the sleeve is inconvenient and time consuming to use.

Another disadvantage associated with existing irrigation systems is that changing an empty reservoir of fluid is time consuming and inconvenient so that it often interrupts surgery.

It is the object of this invention to provide a simple, self-contained, mobile irrigation system which is capable of providing highly pressurized irrigant; the elimination of irrigant contamination; a large volume of irrigant; its own gas supply through a self-contained method of pressurization; warm irrigant to the operative site; irrigant at a pressure which is sufficient for use in laser surgery; convenient and quick changing of irrigation bags; and quiet operation at less than 40dBA.

SUMMARY OF THE INVENTION

Accordingly, the irrigation system of this invention meets the above-stated objectives and is particularly designed for reducing the risk of patient hypothermia and preventing irrigation fluid contamination. The present invention is adapted to provide improved, adjustable flow rates for use during laser surgery which requires higher fluid pressure to create a fluid film barrier to control laser penetration depth.

The irrigation system is self contained and provides heated irrigant while eliminating contamination of the sterile system. The system utilizes an air actuated pouch to compress a flexible fluid reservoir. Heating panels with embedded thermistors are located within the pouch to maintain the temperature of the preheated fluid reservoir. The pouch contains an inflatable air bladder that compresses the reservoir and discharges fluid from the reservoir when the bladder is inflated. The fluid is discharged through a tube and a nozzle to an operative site. A support bag surrounds the reservoir allowing the reservoir to be quickly inserted into the pouch so that the

surgical procedure is not interrupted when a new reservoir is required. In addition, the support bag prevents the reservoir from being pinched during inflation of the pouch.

The pouch is connected to a rigid housing which contains a pump and a control system. The rigid housing has heat and pressure adjustment controls and a display for giving pressure and temperature information. The system operates at reduced noise levels, below about 40dBA, due to the positioning of the pump within the housing. By employing a pump, the system operates independently of the hospital gas lines; thus, making the gas lines available for other uses. Another advantage of the present invention is that it is lightweight and can be attached to an intravenous ("IV") pole where it is not underfoot and user adjustments can be easily made.

The control system utilizes a microcontroller, a pump, a pressure sensor, and a solenoid valve to regulate fluid pressure. In addition, the control system reads and displays the pressure and temperature. Positive pressure is maintained on the fluid for preventing cross-flow contamination of the system.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a perspective view of the irrigation system attached to an IV pole.

FIG. 2 is a perspective view of the support bag.

FIG. 3 is a sectional view of the pouch taken along line 3-3 of FIG. 1.

FIG. 4 is a plan view of a laid out air bladder.

FIG. 5 is a perspective view of the operative instrument.

FIG. 6 is a close up view of a disengaged locking piercing pin and receiver system.

FIG. 6A is a close up view of the locking piercing pin and receiver system of FIG. 6 in the engaged position.

FIG. 7 is a schematic diagram illustrating the electrical connections.

FIG. 8 is a a perspective view of an alternative embodiment of the pouch.

FIG. 9 is a cross sectional view of the pouch of FIG. 8 taken along line 9-9.

FIG. 10 is a perspective view of a bag carrier of the alternative embodiment of the pouch, the bag carrier containing a fluid reservoir and having its door in the closed position.

FIG. 11 is a perspective view of the bag carrier of FIG. 10 with its door in the open position.

FIG. 12 is a perspective view of the front of a bag support of the alternative embodiment of the pouch.

FIG. 13 is a elevational view of the back of the bag support shown in FIG. 12.

FIG. 14 is an elevational view of the assembled pouch of the alternative embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings, FIG. 1 illustrates a surgical irrigation system (10) that reduces the risk of patient hypothermia and prevents fluid contamination during surgery. The irrigation system is lightweight and self contained so that it is quiet, hangs from a standard IV pole (82), and operates independently of hospital gas lines (not shown). Irrigation system (10) comprises a control system (20) and an air actuated pouch (30). Air actuated pouch (30) is particularly designed for use as part

of an irrigation system, but could be used in other applications requiring pressurized fluid.

As shown in FIG. 2, irrigation fluid (76) is contained in a flexible fluid reservoir (32). The reservoir is a standard three liter or a one liter bag of preheated, sterile irrigation fluid. However, three liter bags are more convenient because less frequent bag changing is required. Reservoir (32) further comprises a receiver (100) portion of a standard stick fitting (34) for discharging fluid from the bag without introducing contaminants into the fluid. A piercing pin (96) attached to a tube (52) is inserted into receiver (100) for discharging the fluid. A locking piercing pin and receiver system is illustrated in FIG. 6 and FIG. 6A and discussed in detail below. Reservoir (32) is sterilized and packaged so as to maintain sterility until the fluid is discharged to an operative site.

Reservoir (32) fits within a support bag (36) so that reservoir (32) can be easily and quickly inserted into pouch (30) and to prevent pinching of reservoir (32) during inflation. The support bag (36) is sized so that it closely corresponds to the size of the reservoir (32) so that adequate pressure is applied to the entire reservoir. An opening (38) in the bottom of support bag (36) is aligned with receiver (100). The support bag (36) has a rigid ring for constraining the fluid reservoir in two directions, along two axes, so that fluid is forced out of the reservoir and the reservoir cannot escape the pressure forces exerted upon it. The support bag (36) is flexible along its third axis for compressing the reservoir and has a fastener, preferably a hook and loop type, for securely containing the reservoir.

As shown in FIG. 3, support bag (36) fits within pouch (30). Pouch (30) has an inside cavity (51) for containing support bag (36), an interior surface (48), a mouth (49), at least one air bladder (42) for compressing reservoir (32), at least one flexible heating panel (40) for maintaining the temperature of the preheated irrigation fluid, a receptacle (47) for aligning with stick fitting (34) and support bag opening (38), a cover flap (44) for sealing reservoir (32) within the pouch, and fastening means (39) on cover flap (44) and pouch (30) for securely closing pouch (30).

Pouch (30) contains at least one air bladder (42) secured to pouch interior surface (48) of pouch inside cavity (51). Although various air bladder designs are possible, the preferred embodiment of the air bladder is shown in FIG. 4. Air bladder (42) has four chambers (42A-D). As chambers (42A-D) are inflated, reservoir (32) is compressed such that fluid is pressurized and discharged through stick fitting (34). The number of chambers (42A-D) are based on the strength of the seams of the bladder (42), and one skilled in the art may readily determine the number of chambers required.

Suitable air bladders (42) are urethane film sheets that have nylon laminated to the urethane to provide strength and puncture resistance. The laminate is RF welded so that chambers (42A-D) are formed as shown in FIG. 4. The bladder (42) has an opening (60) for aligning with receiver (100) of fluid reservoir (32). Bladder (42) may be attached to pouch interior surface (48) by various means, however, a suitable method is by sewing the bladder (42) onto pouch interior surface (48).

Chambers (42A-D) are connected by channels (43) such that they can be evenly and simultaneously inflated, and thus, provide even distribution of pressure on reservoir (32). Channels (43) are formed by RF welding portions of the laminate. Connector locations (58) are RF welded circles for connections of an air feed line (57) and an air sensor line (64) from the control system (20) to inflate bladder (42). Although FIG. 3 shows a single air bladder (42) having a front portion (61) and a back portion (62), suitable designs having two, four, six or more separate bladders are possible. Support bag (36) and pouch (30) can be made out of any inelastic fabric, however, reinforced nylon material provides easy and quick insertion of the support bag into the pouch for easy reservoir changing.

Heating panels (40, 41) are disposed on bladder (42) such that one panel (40) is located on front portion (61) and the other panel (41) is located on back portion (62). Alternatively, heating panels (40, 41) may be attached to support bag (36) (not shown) or to pouch inside cavity (51) (not shown) if desired. A desirable temperature

range of the heating panels (40, 41) is about 85° F to about 115° F. However, the fluid temperature is usually maintained at about 98°F to about 100°F to reduce the risk of patient hypothermia.

A suitable heating panel (40,41) is constructed of mylar film having thermistors (not shown) embedded in the panels for regulating the temperature of the heating panels. Heating panels (40, 41) may be attached to bladder (42) (or other structures) by various means, however, a suitable means is by sewing. Heating panels (40, 41) are connected to control system (20) by heater cable (66).

A volume sensor is disposed upon the support bag (36) for sensing and indicating when the amount of fluid in the reservoir (32) has decreased below a certain level. Opposing parts of the sensor are located on opposing sides of the support bag (36) so that the distance between the sensor parts is measured through the compressed fluid. When the distance between the two sensor parts is below a predetermined threshold level, a warning is indicated on the monitor so that a new bag of fluid may be supplied. Although there are several suitable methods for securely fastening pouch (30), a desirable method is shown in FIG. 1 and FIG. 3 where fastening means (39) is high strength hook and loop fastener strips that are disposed on cover flap (44) and pouch (30).

As shown in FIG. 1 and FIG. 5, irrigation system (10) further comprises an irrigation nozzle (55) for discharging irrigation fluid to an operative site (not shown), a flexible tube (52) having a piercing pin (96) at an end opposite nozzle (55) for connecting the nozzle to reservoir (32) by inserting the pin into receiver (100) and piercing the reservoir, and a vacuum line (74) for connecting to a hospital aspiration system.

A preferred embodiment is shown in FIG. 6 and FIG. 6A that prevents piercing pin (96) from being pushed or knocked out of receiver (100). A locking piercing pin and receiver system (90) is employed to prevent tubing (52) from being pushed out of reservoir (32) by either pressure or reservoir movement during inflation, or by accidental movement of reservoir (32). Locking piercing pin and receiver system

(90) comprises a locking receiver (92) attached to pouch (30) and a locking piercing pin (96) attached to tubing (52). Locking receiver (92) has a receiver plate (102) for attaching to pouch (30) and surrounding pouch receptacle (47). Locking receiver (92) extends from plate (102) surrounding stick fitting receiver (100). Locking piercing pin (96) is a standard stickfitting piercing pin, but has locking lugs (98) attached to tubing (52).

To connect tubing (52) to fluid reservoir (32), a user grasps grip openings (94) which are located on locking receiver (92) and inserts piercing pin (96) into receiver (100). Locking lugs (98) should be aligned with locking lug openings (104) so that lugs (98) slip into openings (104) as piercing pin (96) inserts into receiver (100). Locking lugs (98) are then turned so that they are locked into opening (104) and piercing pin (96) can not be inadvertently removed from receiver (100).

Control system (20) is located in a rigid housing (22) having handles (24) located on the housing for easy transport. As shown in FIG. 7, control system (20) is a microcontroller (53) which is electrically connected to a pump (54) for inflating the pouch, a pressure sensor (56) for monitoring pressure, a solenoid valve (59) for regulating pressure, thermistors in the heating panels (40, 41) for regulating temperature, a power supply (80), a display (78) for displaying temperature and pressure readings, and adjustment switches (80) for adjusting pressure and temperature. The system pressure is adjustable from about 0 mm Hg to about 800 mm Hg. A suitable pressure sensor is a Honeywell Micro Switch 180PC series solid state or a Motorola MPX5100 series piezoresistive transducer. A Medo pump is desirable because it is faster than other models and capable of working with simpler control systems.

As illustrated in FIG. 1, FIG. 3, FIG. 5 and FIG. 7, microcontroller (53) activates pump (54) and regulates solenoid valve (59) which allows air to be pumped through air feed line (57) extending from pump (54) to air bladder (42) in pouch (30). As bladder (42) inflates, it compresses reservoir (32) and sterile irrigant (76) is discharged under pressure through stick fitting (34), into tube (52), and into nozzle

(51) to be delivered to the operative site. An air sensor line (64) extends from pressure sensor (56) to air bladder (42) for monitoring pressure. Microcontroller (52) switches heating panels (40, 41) on and off through heater cable (66).

Various means of attaching pouch (30) to said control system (20) exist for suspending the unit from an I.V. pole; however, a suitable mechanism is shown in FIG. 1. Pouch (30) is inserted into take up reel (70). Take up wheel (68) is turned so that pouch (30) is secured around reel (70). Reel lock (72) is secured so that gravity will not cause pouch (30) to unwind from reel (70).

An alternative and preferred embodiment of air activated pouch (30) is depicted in FIGs. 8 - 14. FIGs. 8 and 9 show the pouch (30) and a cross sectional view of pouch (30), respectively. The pouch (30) preferably is formed in a doughnut shape for containing a carrier bag (discussed and shown below) which has an inside cavity (discussed and shown below) for receiving a fluid reservoir (not shown) and a bag support (shown and discussed below). The pouch (30) has an (second) inflatable cavity (240) which houses a bladder (250) having a plurality of chambers, preferably two chambers (250a, 250b), as shown. The chambers (250a, 250b) are interconnected by an interconnecting channel (260) for evenly inflating the bladder (250). The interconnecting channel (260) has air lines (270a, 270b) that connect to the pump (not shown). Furthermore, pouch (30) has fastening means (360) disposed thereon for attaching the bag support which is discussed below.

FIG. 10 illustrates the bag carrier (200) having an inside cavity (220) which is formed by a flexible wall and houses a fluid reservoir (32). The fluid reservoir leads (280a, 280b) extend through openings (370a, 370b) in the bag carrier (200). The bag carrier (200) has a flexible flap or door (290), shown here in the closed position, and secured by, for example, hook and loop type fasteners (300). The bag carrier (200) is sized to correspond closely with the size of the fluid reservoir (32) used (generally either 1 liter or 3 liter).

FIG. 11 shows the bag carrier (200) with its door (290) in the open position for loading or unloading a fluid reservoir (not shown). While the carrier (200) is deformable in three mutually perpendicular directions, a reinforcing member (310) is attached to the carrier (200) for restraining movement of the fluid reservoir in two (indicated by arrows G and H) of the three mutually perpendicular directions. Movement in the third (arrow I) perpendicular direction is allowed and this is the force that compresses the reservoir. The reinforcing member (310) may be made of any suitably rigid material, however, a microwaveable material, such as a rigid plastic, is especially desirable so that the reservoir may be heated in a microwave oven prior to use. In addition, bag carrier (200) has a handle (320) for easy removal of the carrier from the pouch (30).

FIGs. 12 and 13 show a bag support (330) which fits inside pouch (30) and into which the bag carrier (200) is insertable. The bag support (330) houses a sensory device (340a, 340b) and a heating panel (40) which are connected to a power source (not shown) by a power line (380). The sensory device (340) is comprised of two parts (340a and 340b) which are disposed on opposing walls of the bag support (330) for measuring the distance between the opposing walls of the carrier (200) in the third perpendicular direction (I on FIG. 11) for determining the fluid level in the reservoir and generating a signal when the amount of fluid drops below a predetermined level. An example of a suitable sensory device is a Reed switch which employs a magnet in one part of the device (e.g., 340a) and metal in the other part (e.g., 340b) so that when the two parts come within a predetermined proximity of each other a magnetic field is formed which generates a current that sends a signal. While many different types of sensory devices are suitable, this particular device is preferred because it measures the amount of fluid in the reservoir by measuring the distance between the two sensory device parts (340a, 340b) while the reinforcing member (310) and pressure keep substantially all of the fluid between the sensory device parts (340a, 340b) so that the reading is accurate. One part of the sensory device (340a) is disposed on one side of the bag support as shown in FIG. 12, while the other part of the sensory device (340b) and the heating panel (40) are disposed on the opposing side of the bag support as shown in FIG. 13. As shown in FIG. 12, the bag support

(330) has an opening (350) through which the fluid reservoir leads may extend. Preferably, the bag support (330) has fasteners (360) which correspond to the fasteners (360) on the pouch (30) for securing the bag support (330) within and to the pouch (30). Conceivably, the bag support (330) and pouch (30) can be permanently attached or constructed from the same piece of material, however, having a separable bag support (330) provides easy access to the heating panel (40) and sensory device (340) for servicing and modification.

FIG. 14 shows the pouch (30) fully assembled with the carrier (200) and the bag support (330) secured therein. Preferably, the fasteners (360) are hook and loop type fasteners which connect to corresponding fasteners on the outside of the pouch (30). A pressure sensor line (390) and an air feed line (400) are shown for connecting the assembly to the main unit.

While a particular embodiment of the present invention has been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention. It is, therefore, intended to cover in the appended claims all such changes and modifications that are within the scope of this invention.

What is claimed is:

1. A surgical apparatus, comprising:

a flexible pouch having a substantially enclosed inside cavity defined by at least one flexible wall which forms a bag carrier for containing and substantially fully enclosing at least bottom and side surfaces of a disposable flexible fluid reservoir, said carrier being flexibly deformable in three mutually perpendicular directions and having a reinforcing member which restrains movement of said fluid reservoir in only two of the three mutually perpendicular directions while allowing movement in the third perpendicular direction, said pouch further comprising a second cavity exterior to said bag carrier, said second cavity being inflatable for receiving a pressurized fluid and applying a compressive force against said carrier in said third perpendicular direction.

2. The apparatus of claim 1, wherein said pouch further comprises a sensory device for measuring the distance between opposing walls of said carrier in said third perpendicular direction for determining the level of fluid in said reservoir.

3. The apparatus of claim 2, wherein said sensory device generates a signal whenever said distance between opposing walls of said carrier in said third perpendicular direction falls below a predetermined value.

4. The apparatus of claim 1, wherein said reinforcing member comprises a planar and rigid elongated member, said member being aligned in a plane that extends in the same two perpendicular directions as the movement of said reservoir is restrained.

5. The apparatus of claim 4, wherein said reinforcing member forms a closed loop.

6. The apparatus of claim 1, wherein said carrier is separable from said pouch.

7. The apparatus of claim 6, wherein at least a portion of said carrier includes a flap which is moveable between predetermined open and closed positions for inserting and removing said reservoir.

8. The apparatus of claim 7, wherein said carrier and said moveable flap further include hook and loop type fasteners for securing said flap to adjacent portions of said carrier when said flap is in its closed position.

9. The apparatus of claim 1, wherein said carrier is sized so as to closely correspond with the size of said fluid reservoir.

10. The apparatus of claim 1, further comprising a heater located in said pouch for heating said reservoir.

11. The apparatus of claim 1, wherein said second cavity includes an inflatable bladder for receiving said pressurized fluid.

12. The apparatus of claim 11, wherein said bladder further comprises a plurality of chambers, said chambers being interconnected by at least one channel for inflating said second cavity evenly.

13. The apparatus of claim 1, wherein said pouch further comprises:

a locking receiver for preventing said flexible tube from disengaging said fluid reservoir; and

said flexible tube comprises a piercing pin located at an end of said tube for penetrating said reservoir and locking lugs located adjacent said piercing pin for fitting into said locking receiver.

14. The apparatus of claim 13, further comprising a nozzle and a flexible tube attached to said nozzle for discharging said fluid from said reservoir to the surgical site.

15. A surgical apparatus, comprising:

a flexible pouch having a substantially enclosed inside cavity defined by at least one flexible wall for containing and substantially fully enclosing at least bottom and side surfaces of a disposable flexible fluid reservoir;

said pouch further comprising a second cavity exterior to said inside cavity, said second cavity being inflatable for receiving a pressurized fluid and applying a compressive force against said at least one flexible wall of said inside cavity; and

said second cavity further comprising a plurality of chambers, said chambers being interconnected by channels for even inflation of said cavity.

16. The apparatus of claim 15, wherein said flexible wall is a bag carrier which is flexibly deformable in three mutually perpendicular directions and has a reinforcing member which restrains movement of said fluid reservoir in only two of the three mutually perpendicular directions while allowing movement in the third perpendicular direction.

17. The apparatus of claim 16, wherein said reinforcing member is a rigid and planar elongated member, said member being aligned in a plane that extends in the same two perpendicular directions as the movement of said reservoir is restrained.

18. The apparatus of claim 15, wherein said carrier is separable from said pouch.

19. The apparatus of claim 16, wherein said pouch further comprises a sensory device for measuring the distance between opposing walls of said carrier in said third perpendicular direction for determining the level of fluid in said reservoir.

20. The apparatus of claim 19, wherein said sensory device generates a signal whenever said distance between opposing walls of said carrier in said third perpendicular direction falls below a predetermined value.

21. The apparatus of claim 15, wherein said second cavity is separable and openable near its top.

22. A surgical apparatus for preventing contamination of irrigation fluid during surgery and reducing the risk of patient hypothermia, comprising:

a flexible pouch having a substantially enclosed inside cavity defined by at least one flexible wall which forms a bag carrier for containing and substantially fully enclosing at least bottom and side surfaces of a disposable flexible fluid reservoir, said carrier being flexibly deformable in three mutually perpendicular directions and having a reinforcing member which restrains movement of said fluid reservoir in only two of the three mutually perpendicular directions while allowing movement in the third perpendicular direction, and said carrier being separable from said pouch, said pouch further comprising a second cavity exterior to said bag carrier, said second cavity being inflatable for receiving a pressurized fluid and applying a compressive force against said carrier in said third perpendicular direction;

a pump for inflating said second cavity;

pressure control means for regulating said pressurized fluid;

a heater for heating said fluid; and

a sensory device located within said pouch for measuring the distance between opposing walls of said carrier in said third perpendicular direction for determining the level of fluid in said reservoir.

23. The surgical apparatus of claim 22, wherein said pouch further comprises:

a locking receiver for preventing said flexible tube from disengaging said fluid reservoir; and

said flexible tube comprises a piercing pin located at an end of said tube for penetrating said reservoir and locking lugs located adjacent said piercing pin for fitting into said locking receiver.

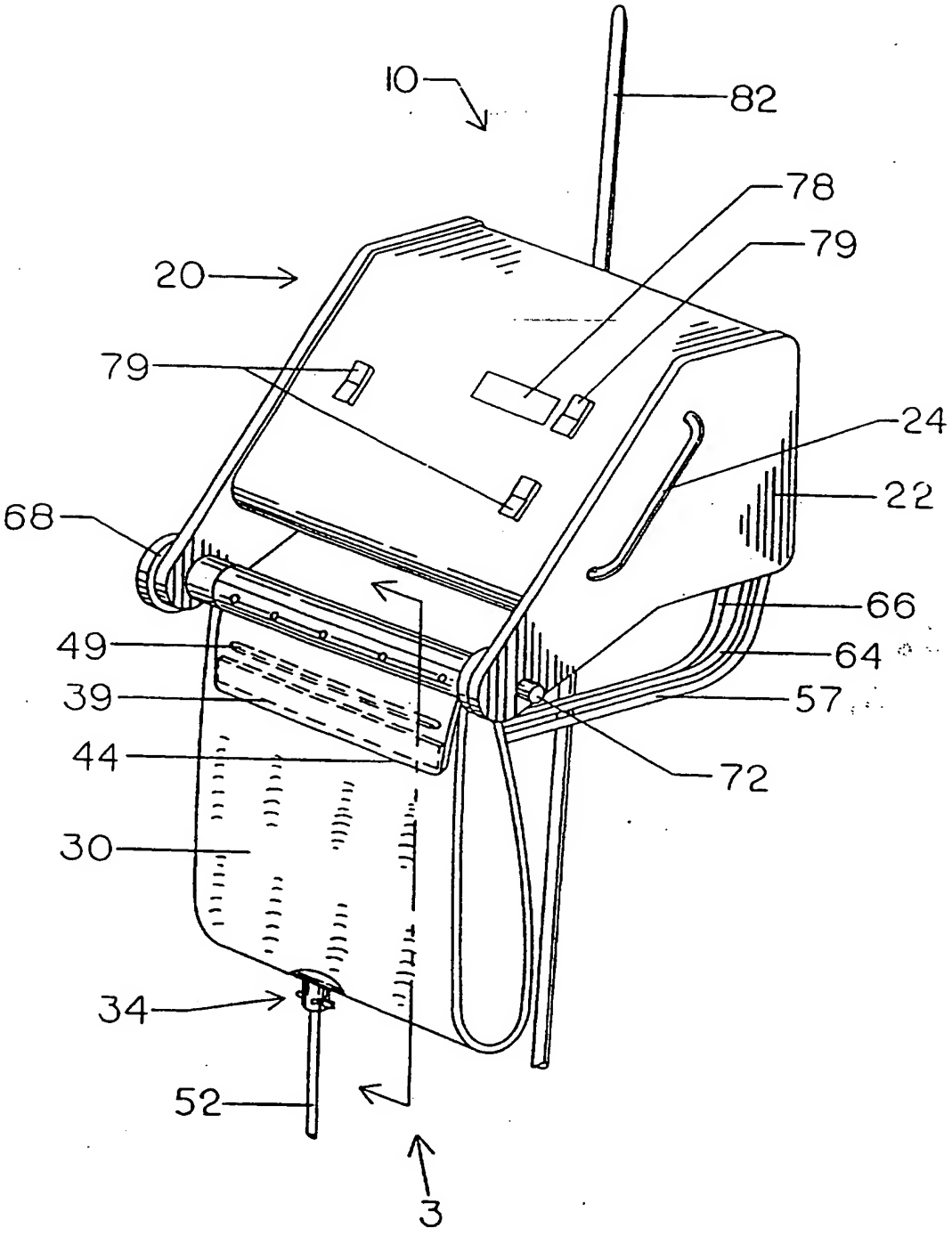


FIG 1

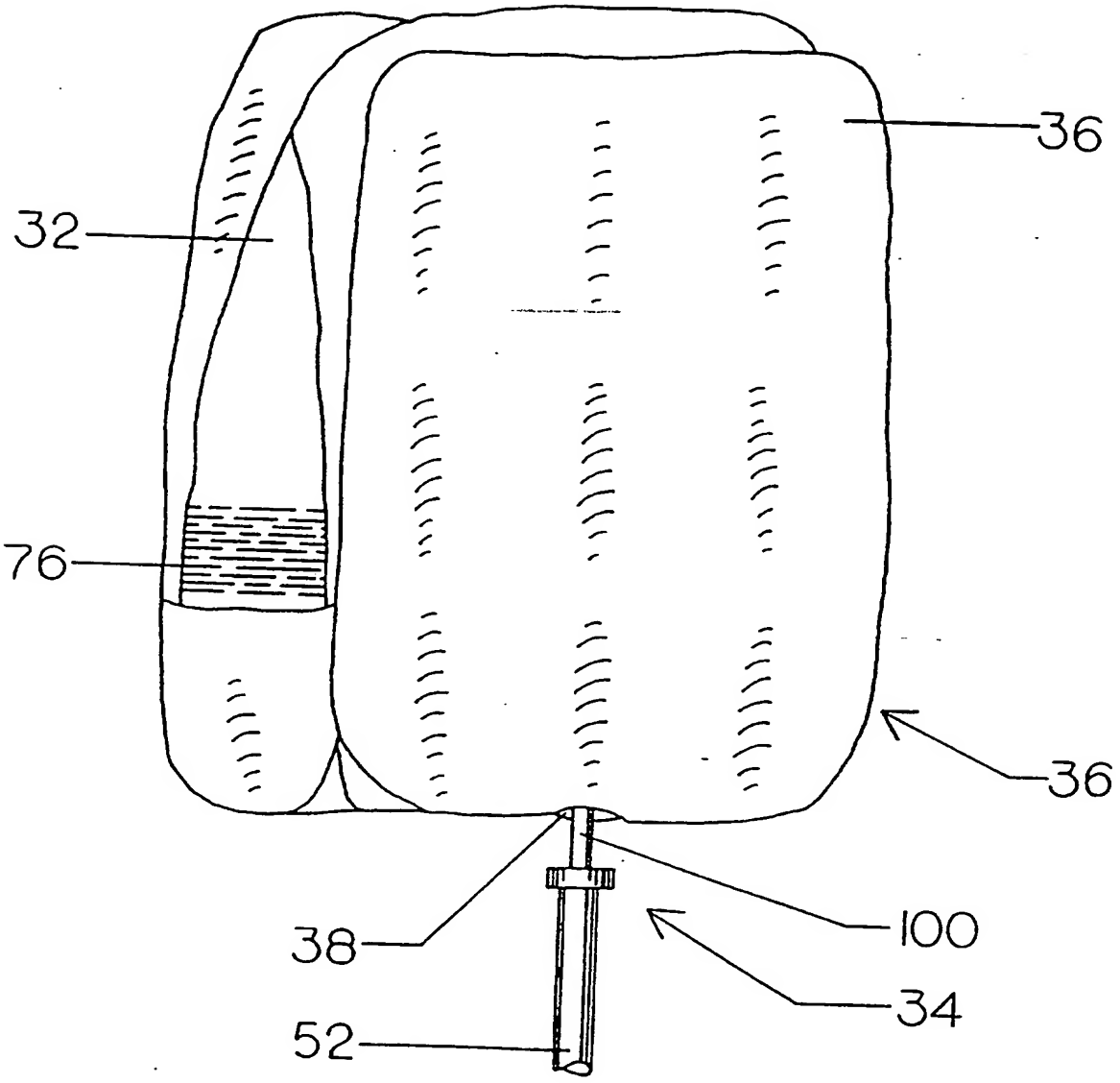


FIG 2

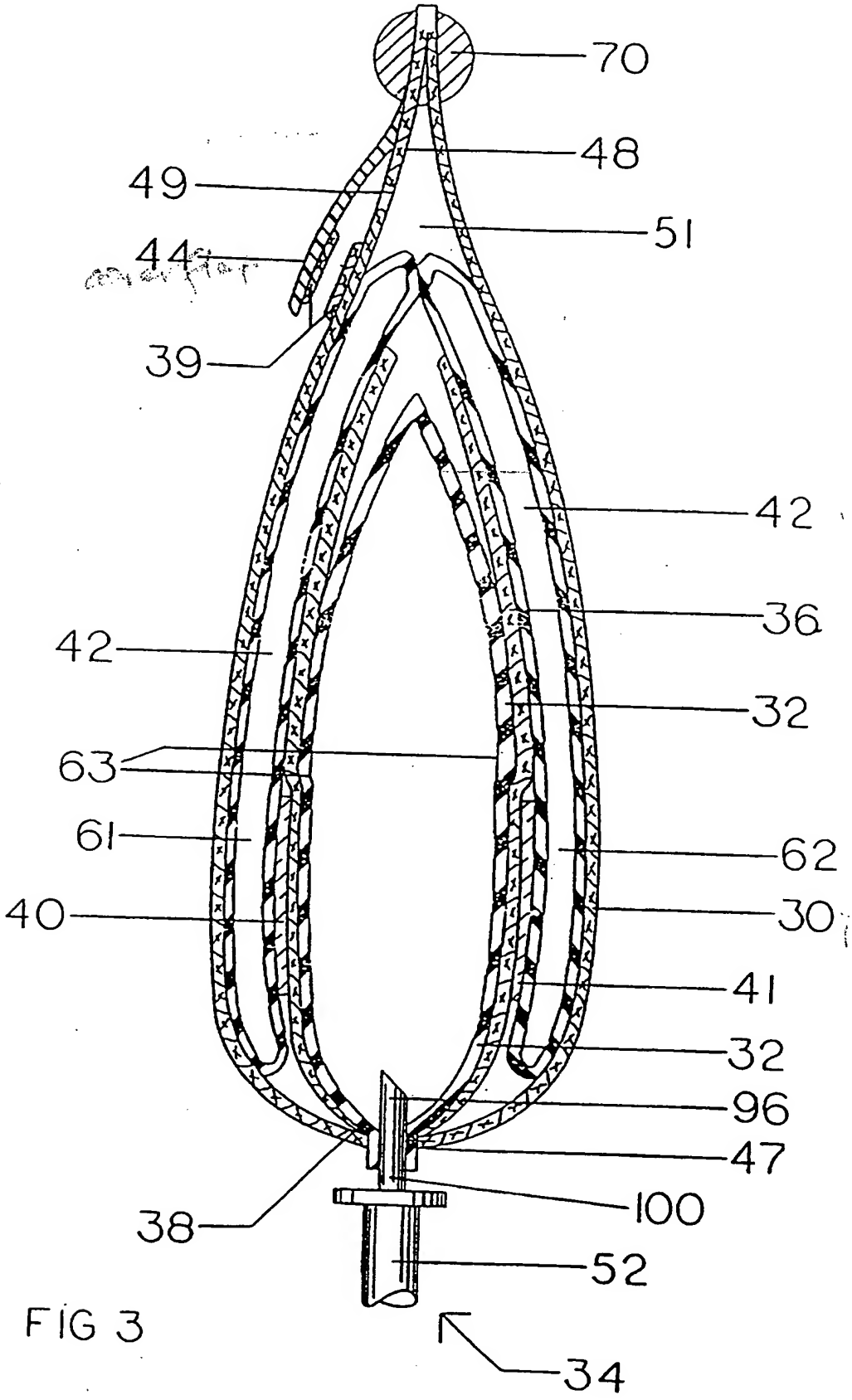


FIG 3

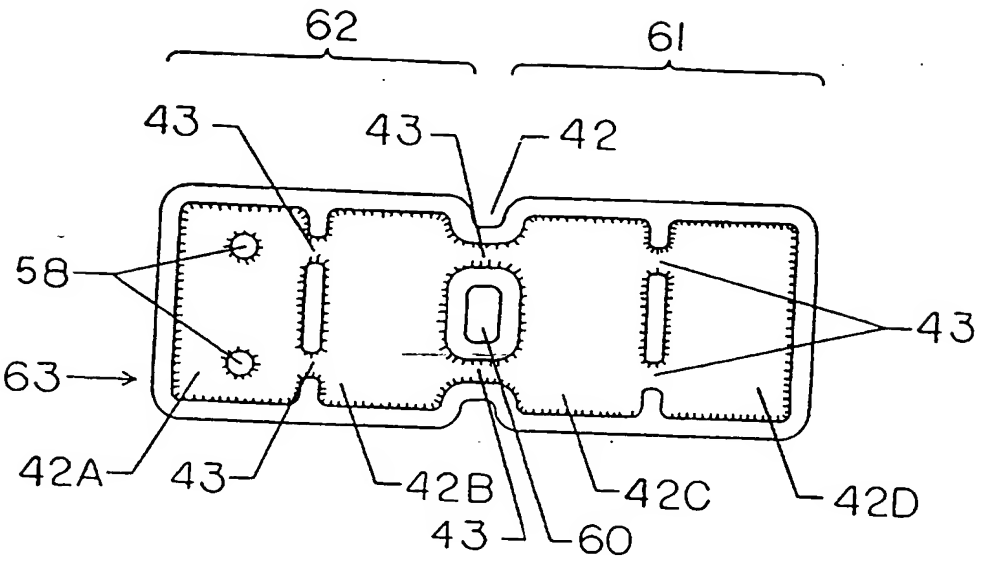


FIG 4

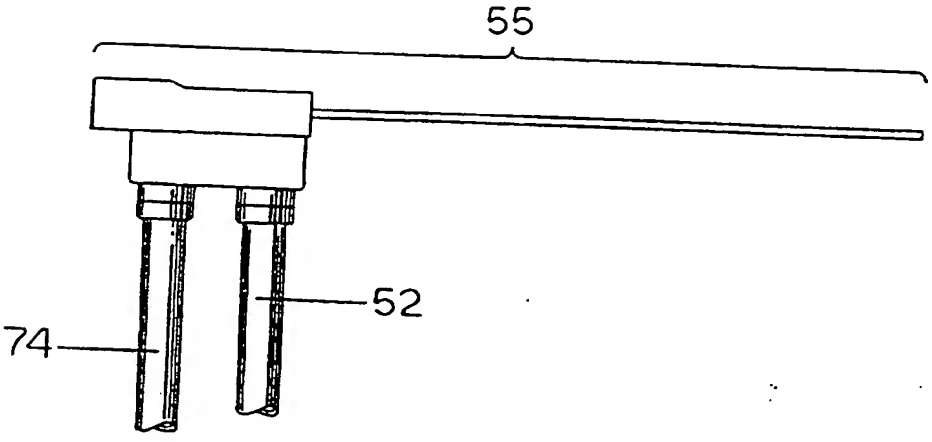
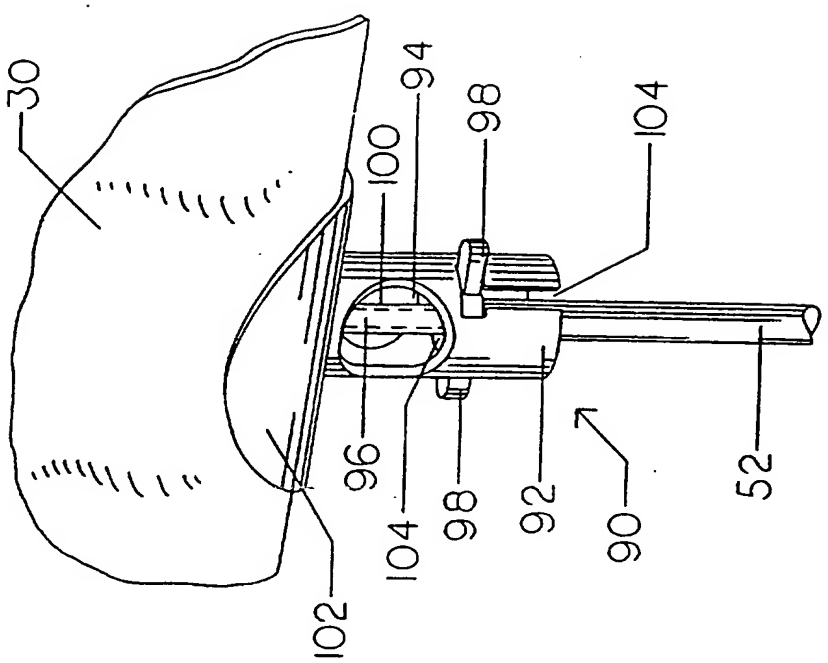


FIG 5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94
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92
90
52
102

FIG 6A

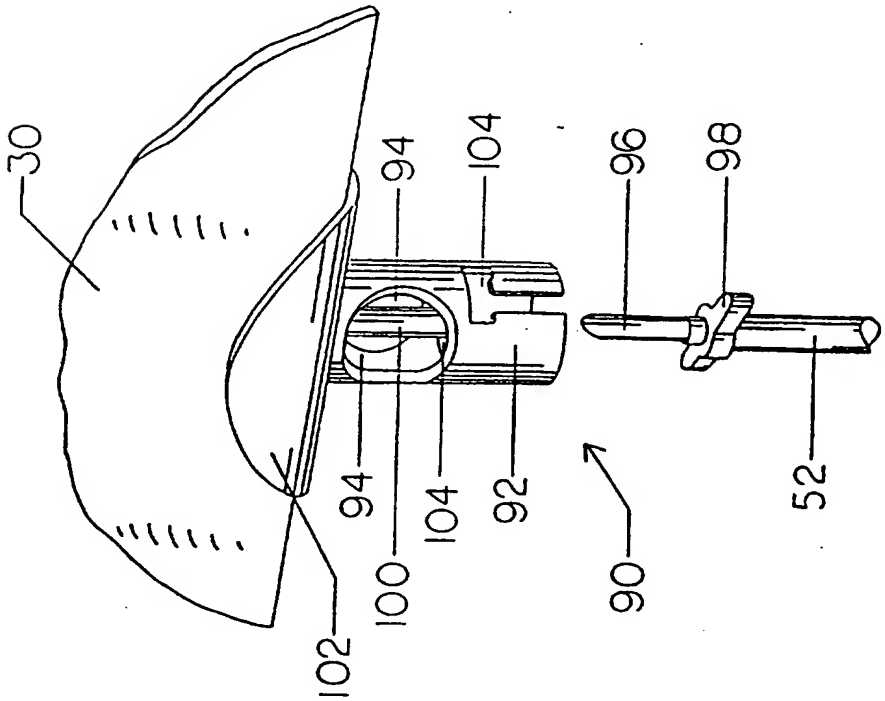
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FIG 6

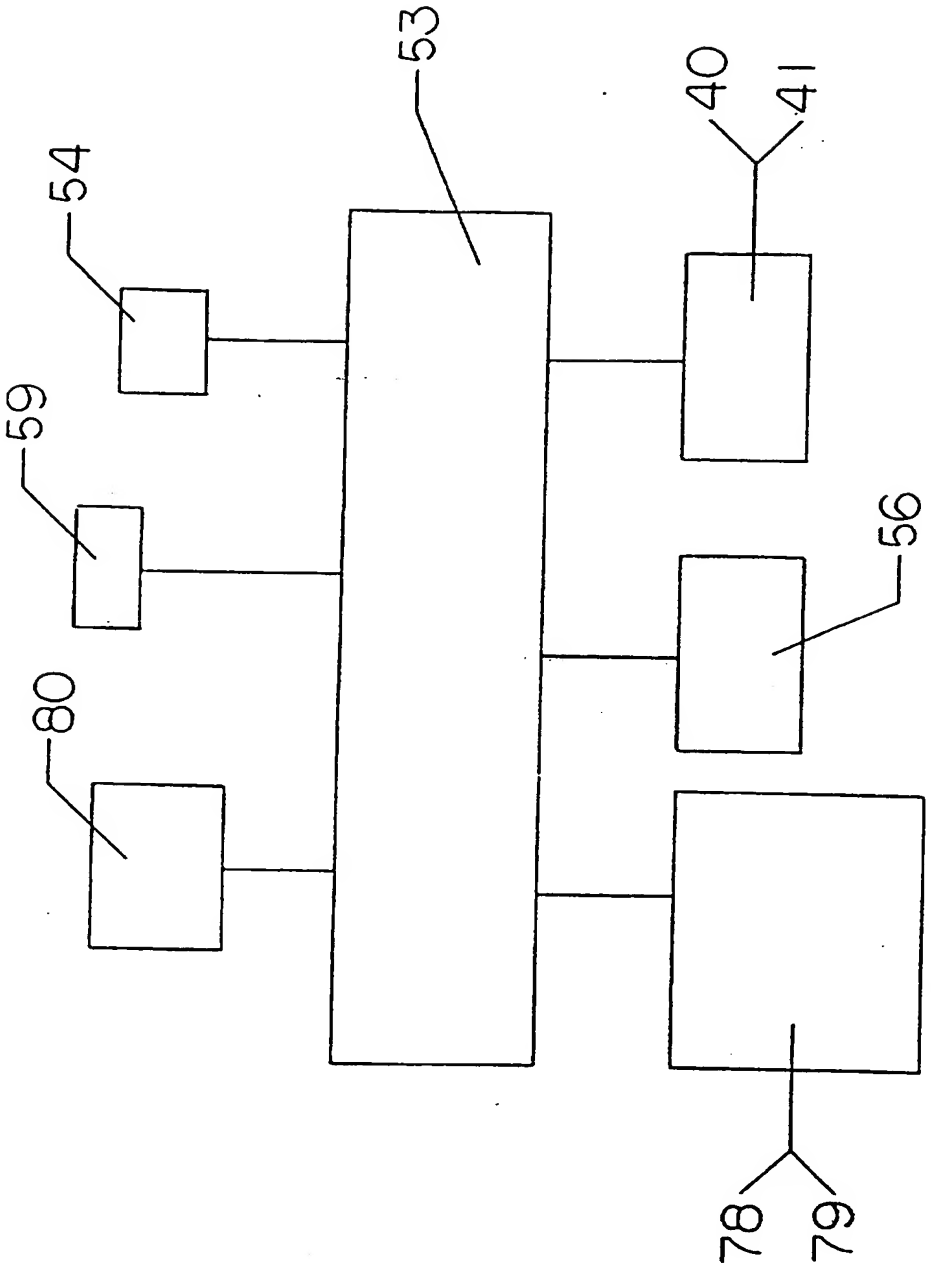

FIG 7

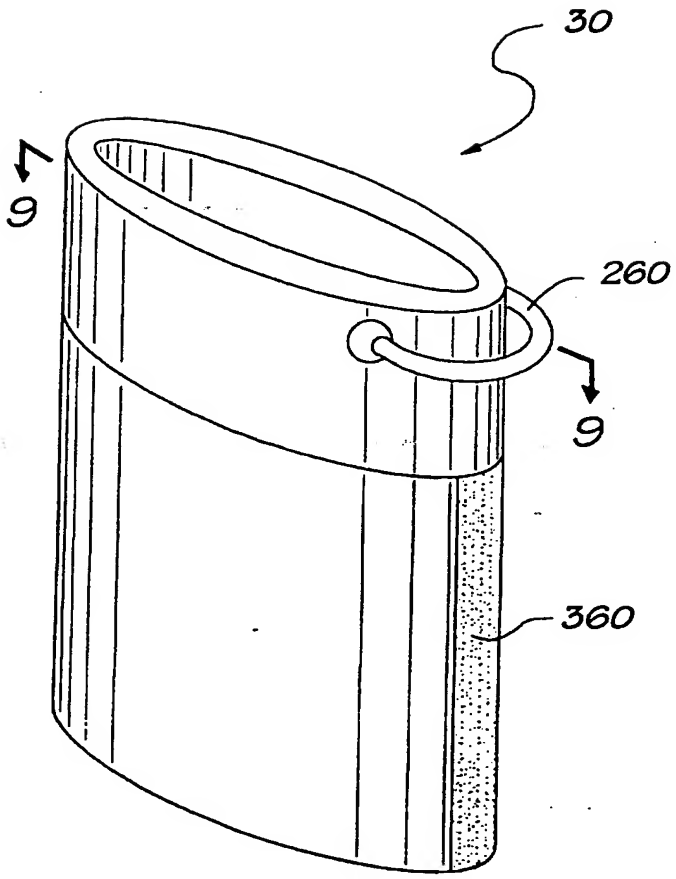

FIG. 8

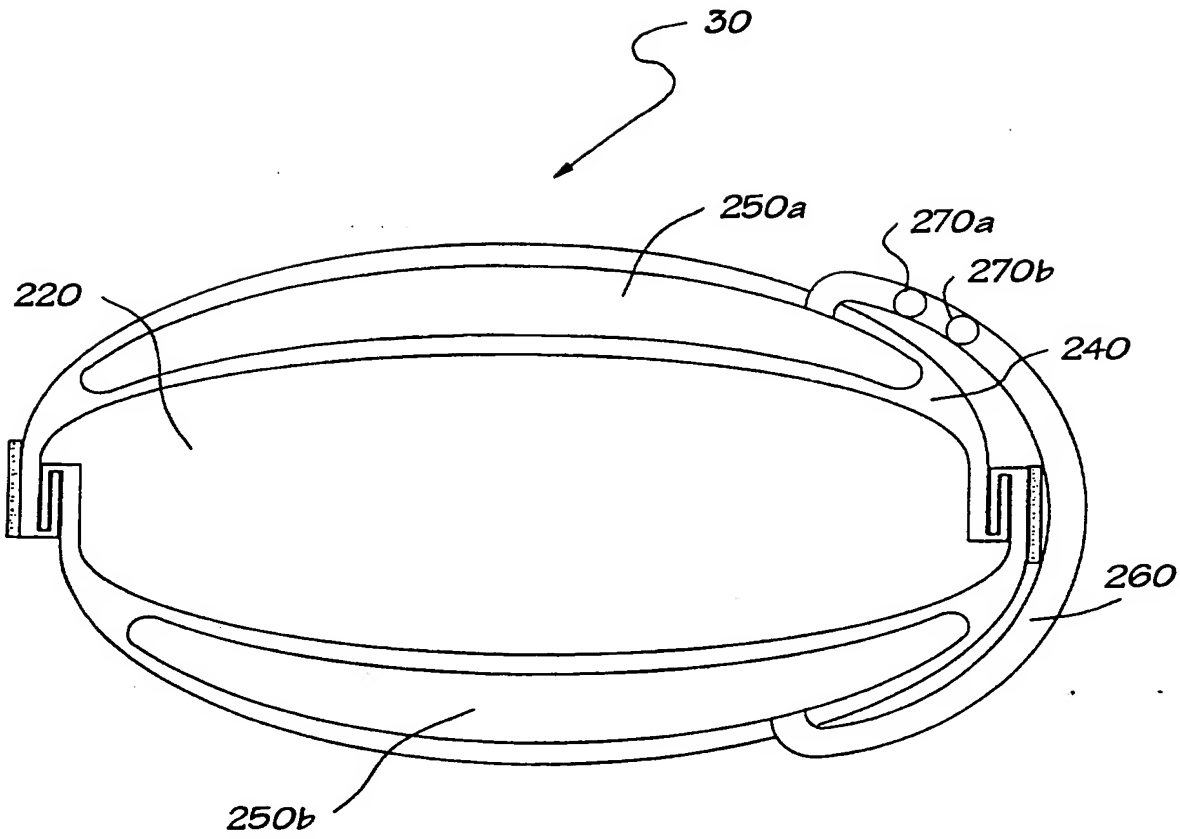

FIG. 9

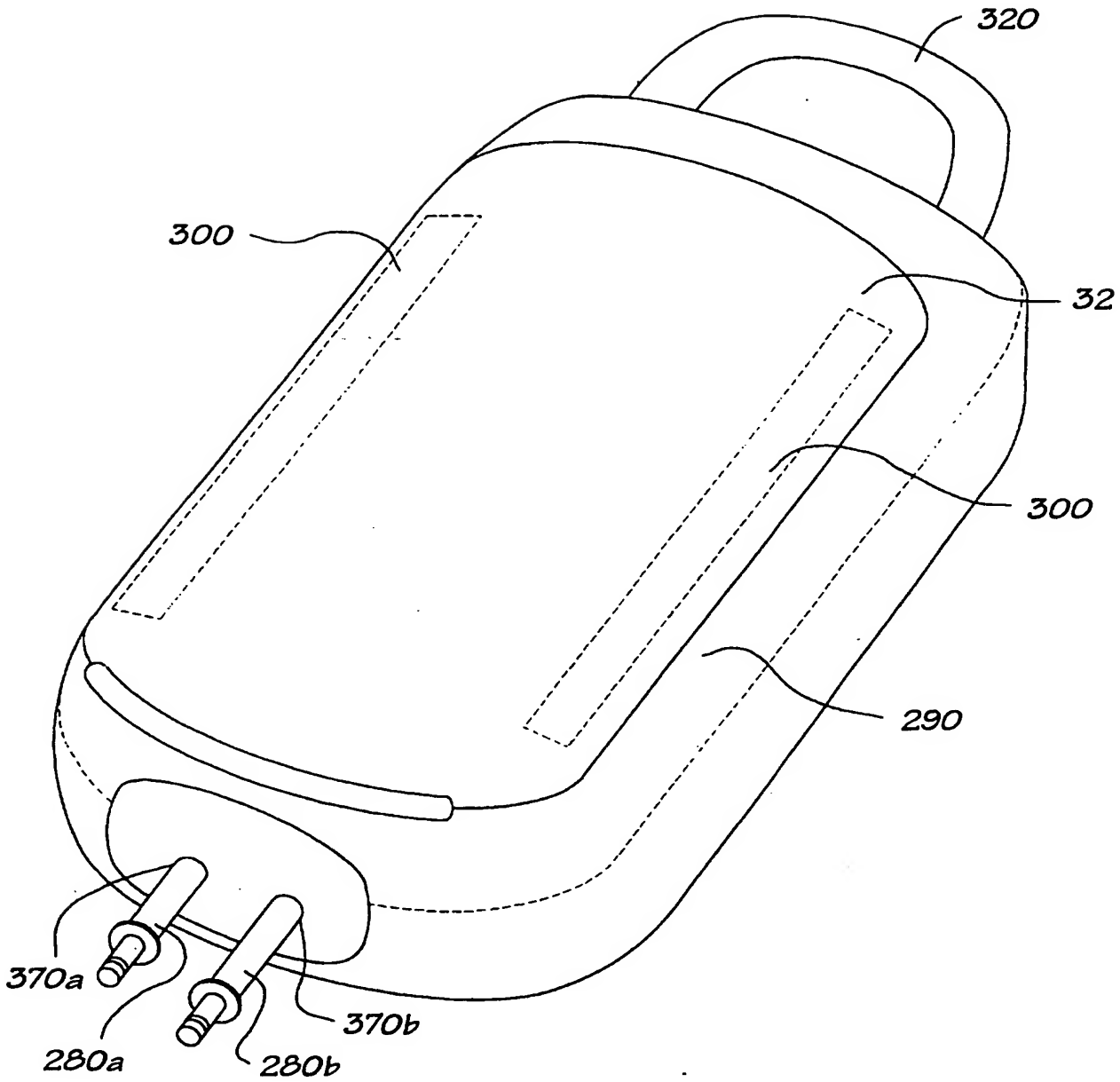

FIG. 10

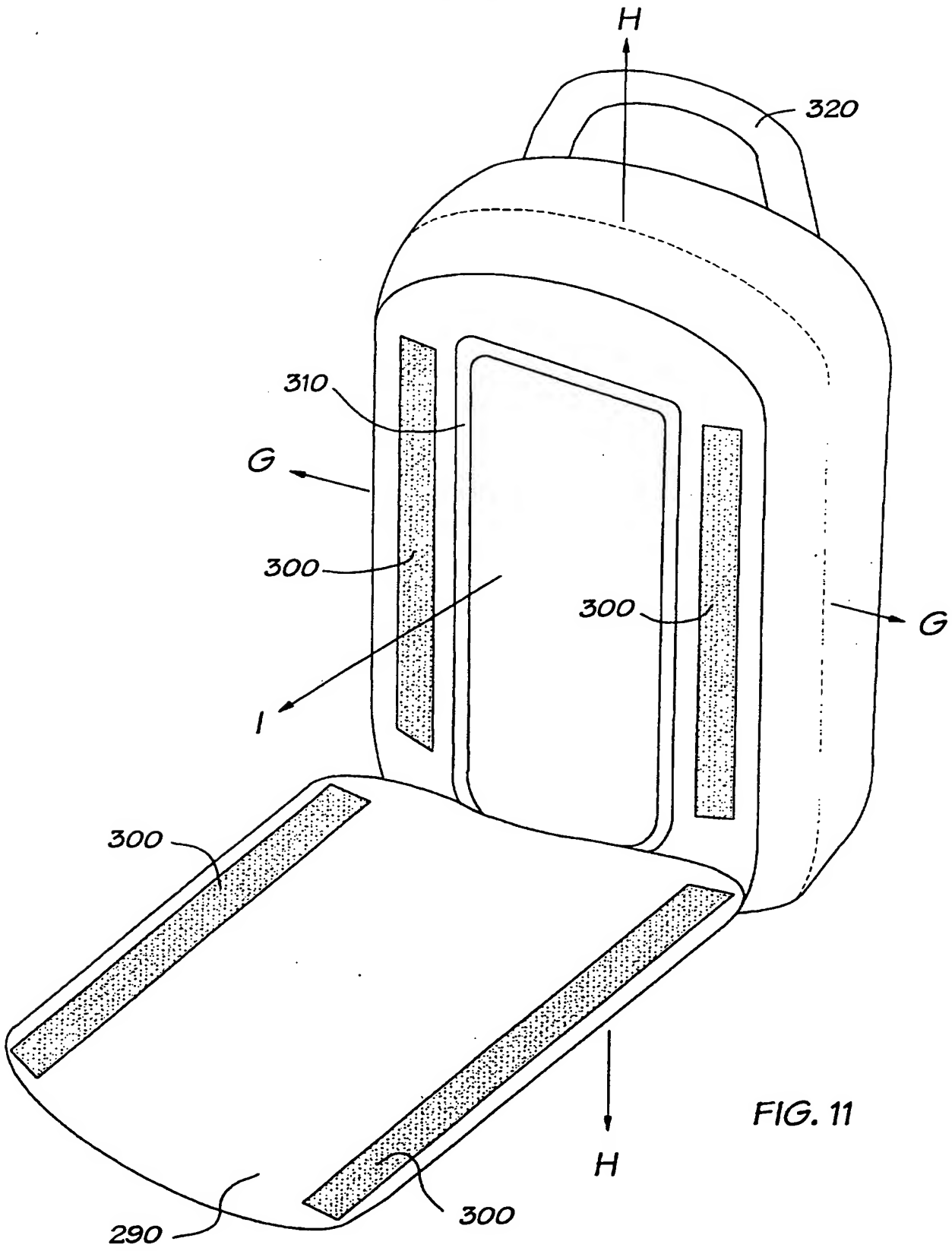

FIG. 11

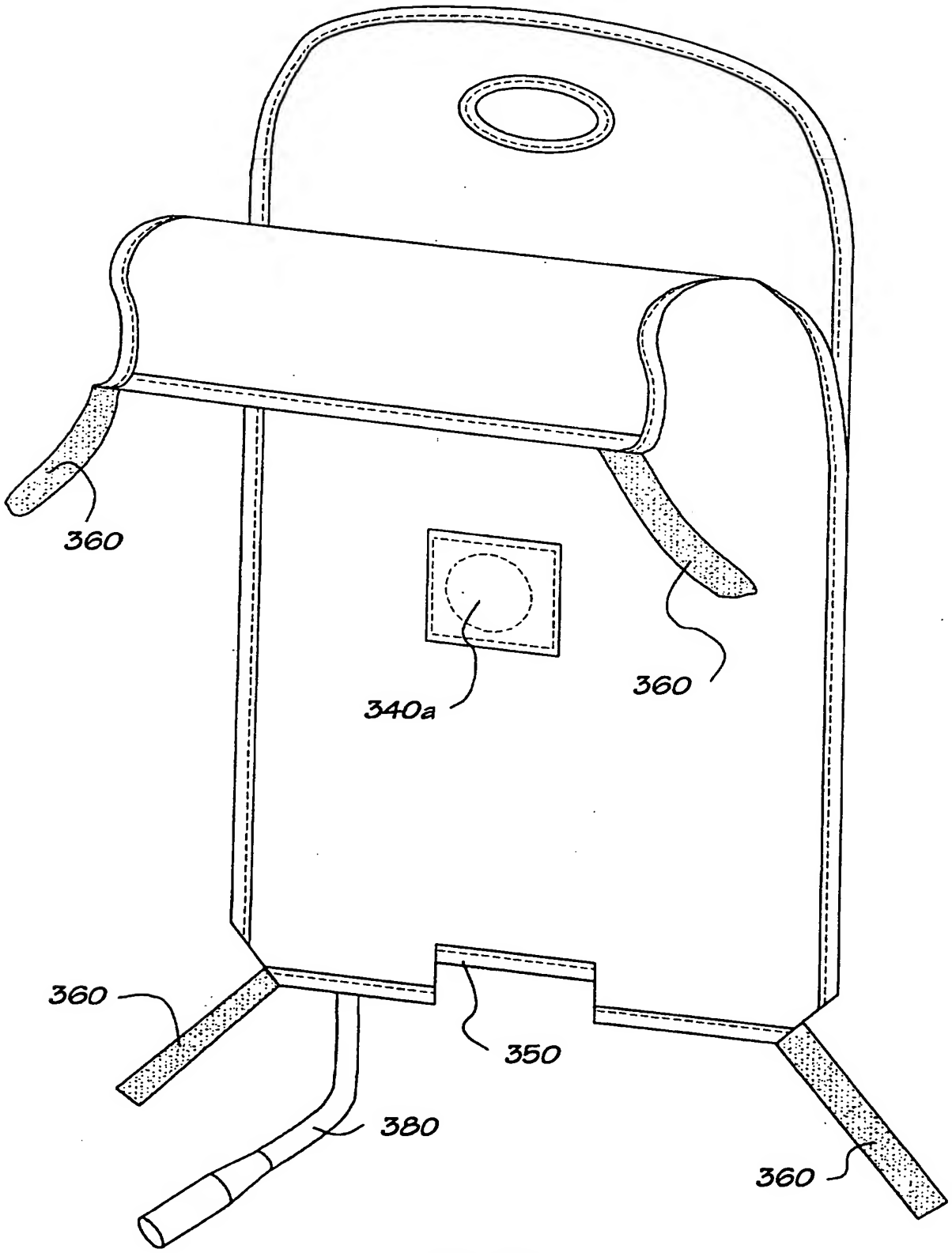

FIG. 12

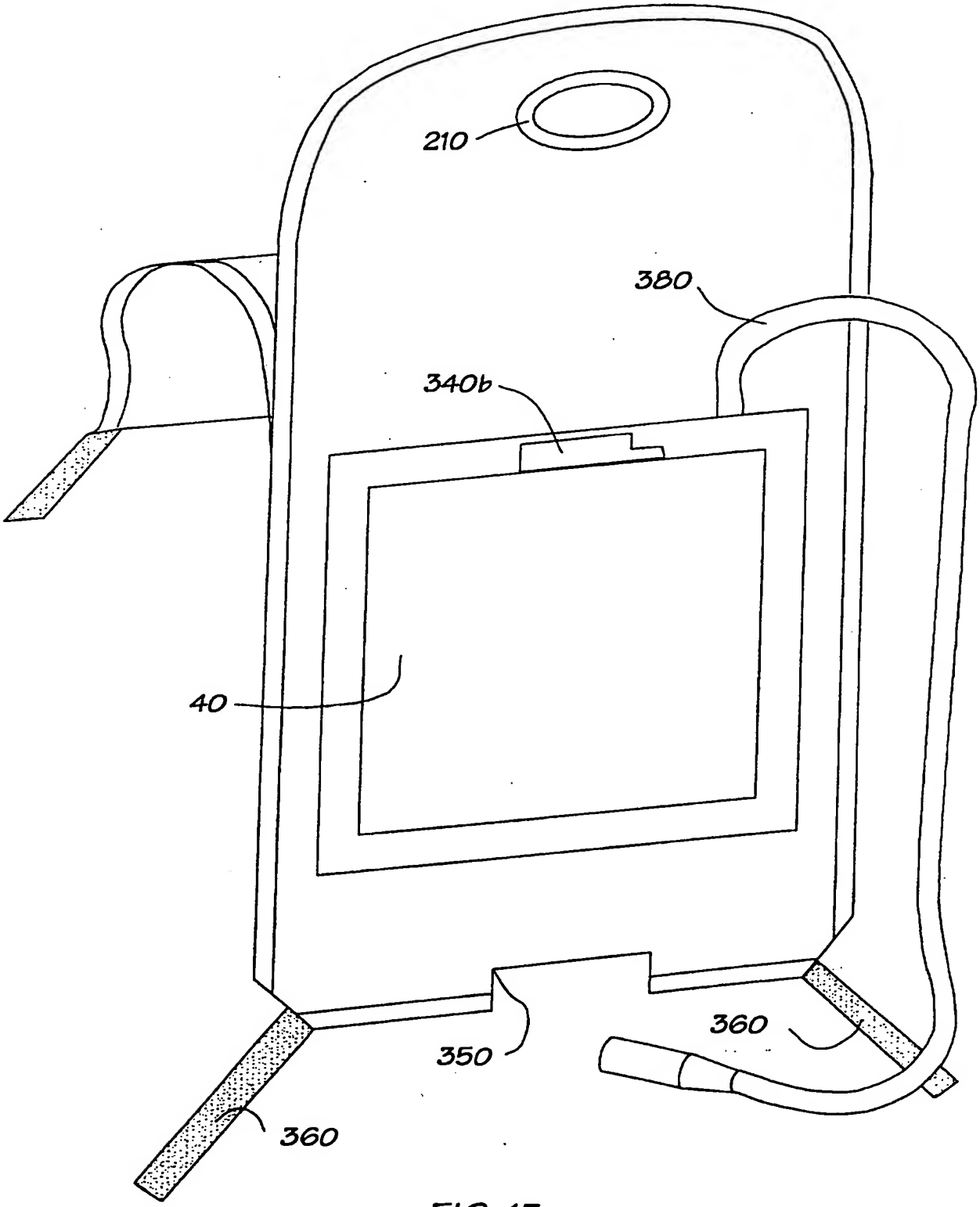

FIG. 13

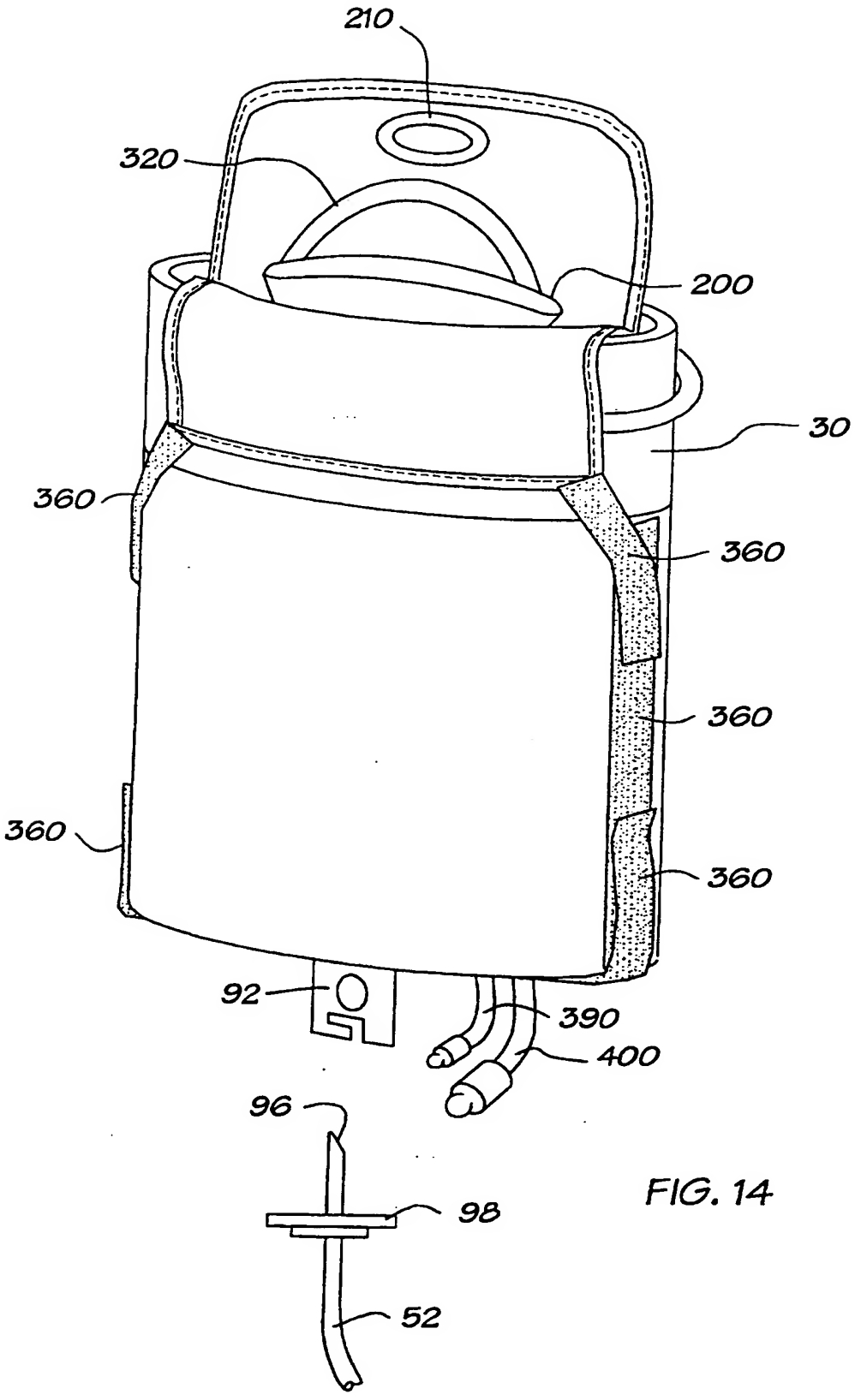

FIG. 14

INTERNATIONAL SEARCH REPORT

Internatic \pplication No
PCT/US [redacted]14985

A. CLASSIFICATION OF SUBJECT MAT[redacted]
IPC 6 A61M5/155

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	EP,A,0 351 344 (P ANTONETTI) 17 January 1990 ---	1,15,22
A	EP,A,0 210 424 (TRANSMED MEDIZINTECHNIK GMBH) 4 February 1987 ---	1,22
A	GB,A,2 118 634 (S LEIBINSOHN) 2 November 1983 ---	1,22
A	WO,A,88 07384 (KANTAL MEDICAL HEATING AB) 6 October 1988 ---	10
A	US,A,4 857 055 (P WANG) 15 August 1989 ---	15
A	US,A,4 613 327 (H TEGRARIAN) 23 September 1986 see column 8, line 57 - line 66 -----	18,19

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 May 1995	24. 05. 95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Vereecke, A

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Internatio ...pplication No
PC[redacted] 94/14985

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